DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Supplemental New Animal Drug Application; Ivermectin and Praziquantel Paste

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Virbac AH, Inc. The supplemental NADA provides for use of an ivermectin and praziquantel oral paste for the treatment and control of various species of internal parasites in mares intended for breeding purposes.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 7613, filed a supplement to approved NADA 141–215 for EQUIMAX (ivermectin 1.87%/praziquantel 14.03%) Paste, used in horses for the treatment and control of various species of internal parasites. The supplemental NADA provides for use of EQUIMAX Paste in mares intended for breeding purposes. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of July 30, 2004. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning July 30, 2004.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 25, 2004

August 25, 2004.

Steven D. Vaughn DVM

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S